REMARKS

In the Office Action dated July 18, 2007, independent claims 1 and 28 were rejected under 35 U.S.C. §102(b) as being anticipated by Brignola (U.S. Patent No. 4,331,146). Dependent claims 2-27 and 29-32 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Landau (U.S. Patent No. 6,264,629) in view of Landau, et al. (U.S. Patent No. 6,132,395), and further in view of Brignola. The Office Action further rejected independent claim 33 under 35 U.S.C. 103(a) as being inherent to the apparatuses of Landau and Landau et al. Each of these rejections is respectfully traversed.

Claim Rejections – 35 USC §102

The Office Action rejected independent claims 1 and 28 under 35 U.S.C. 102(b) as being anticipated by Brignola. Applicants respectfully traverse this rejection. As will be explained in detail below, Brignola does not disclose each and every limitation of claim 1 or claim 28. In particular, Brignola does not disclose a multi-use, needle-free injector assembly or an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice as set forth in claim 1 as presently amended. Therefore, Brignola can not anticipate claim 1 or claim 28.

Legal Standard for Anticipation under 35 U.S.C. § 102(b)

A prima facie case of anticipation "requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock,* 721 F.2d 1540, 220 USPQ 303 (Fed. Cir 1983); *see also* MPEP § 2131. It is not enough, however, that the prior art reference disclose all the claimed elements in isolation. Rather, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.,* 730 F.2d 1452 (Fed. Cir. 1984); *see also In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Furthermore, "[t]he identical invention must be shown in as complete detail as [is] contained in the ... claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Brignola Does Not Disclose Every Limitation of Claim 1

Claim 1 has been amended herein to recite that the injector assembly is a "multi-use needle-free injector assembly." However, Brignola discloses a syringe assembly for administering medication to a patient through a ***hypodermic needle*** (Brignola at 1:16-22, 1:62-66, 3:51-54, 4:17-19). Additionally, Brignola does not describe a multi-use injector. Brignola is not a multi-use injector because (1) it utilizes a needle in order to administer injections to a patient and it is unhygienic to reuse a needle due to the potential for disease transmission, and (2) the seal / diaphragm is broken during the injection, thus it is not reusable (Brignola at 6:61 to 7:14).

Furthermore, as the basis for rejection of claims 1 and 28, the Office Action states that "Brignola shows in figures 14-15, 38-39 and 44-45, a removable cap generally distal to the end orifice, the cap further including a cap distal face and a cap proximal face, and an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice." Applicants respectfully disagree that every limitation of claim 1 as currently amended herein is disclosed in Brignola as required by 35 U.S.C. §102(b).

Figures 14-15, 38-39 and 44-45 (collectively "the Brignola figures"), illustrate a ***non-removable*** thin diaphragm (reference numeral 418 or 820) or plunger wall (830) that prevents the mixing of a powder medicament and a liquid diluent medicament contained in separate containers of a two-container syringe (Brignola at 7:41-45). The Brignola figures show that when a piston plunger, located inside of an inner container that holds the liquid medicament, is depressed, the hydraulic pressure in the inner container increases and the diaphragm at the opposite end of the inner container bursts or opens, thus allowing the liquid medicament to flow into an outer container that is holding the powder medicament (Brignola at 6:61 to 7:14 and 7:41-45). It is then that the powder medicament and liquid medicament diluent are allowed to mix within the syringe ***proximal*** to the injection orifice. Thus, the Brignola diaphragm serves only to prevent the mixing process from occurring inside of the syringe until it is desired by the user. It is not, however, an ***injection prevention component*** as recited in presently amended claim 1 as it does not function to prevent injections from being administered. Indeed, one of the functions of the diaphragm in Brignola is to fail as part of the injection process and not to prevent injection (Brignola at 6:61 to 7:14). Furthermore, the diaphragm disclosed in Brignola is not located ***distal to the distal end orifice***, as recited in claim 1 as presently amended herein. Rather the diaphragm of Brignola is located ***proximal to the distal end orifice***.

Therefore, because Brignola does not disclose a multi-use, needle-free injector nor "an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice," as recited in presently amended claim 1, Brignola can not anticipate claim 1 as presently amended. MPEP § 2131.

Brignola Does Not Disclose Every Limitation of Claim 28

As with currently amended claim 1 discussed above, claim 28 has been amended herein to recite that the injector assembly is a "multi-use needle-free injector assembly." However, Brignola discloses a syringe assembly for administering medication to a patient through a hypodermic needle (Brignola at 1:16-22, 1:62-66, 3:51-54, 4:17-19). Additionally, for reasons explained in relation to claim 1, Brignola also does not disclose a multi-use injector assembly.

In addition, as discussed above, the Office Action states as the basis for rejection of claims 1 and 28 that "Brignola shows in figures 14-15, 38-39 and 44-45, a removable cap generally distal to the end orifice, the cap further including a cap distal face and a cap proximal face, and an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice." However, the Office Action fails to identify how Brignola discloses the "means for preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice" recited in claim 28 as presently amended.

As discussed above regarding claim 1, Brignola discloses a two-container syringe having a diaphragm disposed between the two containers to prevent a powder medicament and a liquid diluent medicament from mixing (Brignola at 7:41-45). Brignola also discloses a manually moveable piston plunger (430a) for increasing the hydraulic pressure of the liquid medicament in the inner container in order to cause the diaphragm to burst and for expelling the mixed medicaments through the needle and into a patient (Brignola at 6:61 to 7:14 and 8:23-31). Brignola does not, however, disclose, either explicitly or inherently, "a means for preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice," as set forth in claim 28 as currently amended. The piston plunger (430a) of Brignola is axially slidable within the inner syringe container (Brignola at 8:23-29) and does not contain any features or elements which would serve either as a means for preventing the injection piston from moving or to provide a locked position for the piston plunger. Furthermore, even if such feature could arguably be construed to exist in Brignola, it would still not satisfy the claim 28 language that the means for preventing the injection from moving is "partially located ***distal*** to the distal end orifice."

Therefore, because Brignola does not disclose a multi-use, needle-free injector assembly as recited in presently amended claim 28, and because Brignola does not disclose "a means for

preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice," as recited in presently amended claim 28, it does not disclose each and every limitation of claim 28 as required by 35 U.S.C. §102(b). As such, Brignola does not anticipate claim 28 as amended herein. MPEP §2131.

Claim Rejections – 35 USC §103(a)

Dependent claims 2-27 and 29-32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Landau in view of Landau, et al., and further in view of Brignola. Independent claim 33 stands rejected under 35 U.S.C. §103(a) as the Office Action considered the cited steps to be inherent to the apparatuses of Landau and Landau et al.

It is well settled that in order to establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the combined prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974). Because the combination of Landau in view of Landau et al. and further in view of Brignola does not teach every feature of independent claims 1 and 28, as well as claims 2-27 and 29-32 which depend therefrom, claims 1-27 and 28-32 are not obvious in view of the combined references.

Landau In View Of Landau et al. and Further In View Of Brignola Does Not Render Claims 2-27 Obvious

Claims 1-27 of the present application specify that the injection prevention component is disposed generally ***proximal*** to the cap distal face and ***distal to the distal end orifice***. As will be explained fully below, the combination of Landau in view of Landau et al. and further in view of Brignola fails to teach or suggest that the injection prevention component is disposed generally proximal to the cap distal face and distal to the distal end orifice.

Landau shows a single-use jet injection device having features that ***prevent leakage*** of an injectable medication while in a storage configuration as well as ***internal*** safety features that prevent expulsion of the medication prior to administering an injection. Specifically, Fig. 3 of Landau shows a plug member 44 located within the outlet orifice 36b of the pre-filled drug injection cartridge 14. This plug member 44 serves to prevent leakage of medication from the injection cartridge 14 and is located ***proximal*** to the injection nozzle opening 18. However,

currently amended claim 1 of the present application specifies that the injection prevention component is disposed generally ***distal*** to the distal end orifice (i.e. the injection nozzle). Accordingly, Landau does not disclose the claim limitation as recited in currently amended claim 1. Moreover, the plug member 44 in Landau is present to sealingly close the outlet orifice 36b of the injection cartridge 14 so as to prevent medication from leaving the device when the injector is in the storage configuration (Landau at 5:63-65) and does not serve to disable the injector and prevent accidental injection. Indeed, whenever an injection in Landau is triggered, the plug member 44 actually allows medication to flow around it and out of the injection orifice (Landau at 8:36-64 and 9:10-22). As such, Landau does not disclose, either explicitly or inherently, the ***injection prevention*** component located ***distal*** to the distal end orifice, as is recited in currently amended claim 1, and accordingly, does not disclose every limitation of claims 2-27 which depend from claim 1.

Landau et al. fails to remedy the shortcomings of Landau. Specifically, Landau et al., just as in Landau, illustrates (Figs. 1-10) a plug-like member, outlet valve 46, 246, 346, and 446, located ***proximal*** to the jet orifice 52 that prevents liquid injectate from leaking out of cartridge/nozzle assembly 10 prior to the cartridge/nozzle assembly 10 being inserted into injector 32. However, upon insertion of cartridge/nozzle assembly 10 into injector 32, increased hydraulic pressure from the insertion process causes outlet valve 46 to move to a forward position, unsealing cartridge 12, and forcing injectate to freely flow to and out of jet orifice 52 (Landau et al. at 5:56 to 6:15) prior to any injection actually occurring. Thereafter, when an injection is triggered, outlet valve 46 is designed to allow injectate to flow around it and out the aperture 52 into a patient (Landau et al. at 6:24-35). Accordingly, outlet valve 46 does not serve as an injection prevention component. Therefore, because the outlet valve 46 of Landau et al. is located ***proximal*** rather than ***distal*** to the distal end orifice, and because it does not serve to prevent injections from occurring, Landau fails to cure the deficiencies of Landau and does not disclose the claim 1 limitation of "an ***injection prevention component*** disposed generally... ***distal*** to the distal end orifice."

Furthermore, Landau et al. also illustrates (Figs. 17A and 17B) and describes (Landau et al. at 7:59 to 8:13) the use of an aluminum seal 568 and an elastomeric membrane 566 to seal the prefilled cartridge 512. The aluminum seal 568 and elastomeric membrane 566 are designed to burst open when loaded into a needleless injector and prepared for use. (Landau et al. at 6:51-

60). Neither the aluminum seal 568 nor the elastomeric membrane 566 of Landau et al. ***prevent injection***, as they are designed to fail in order to facilitate injection and are only present in order the seal the cartridge 512. Accordingly, they do not serve as an ***injection prevention component*** as is recited in amended claim 1. Additionally, the aluminum seal 568 and elastomeric membrane 566 are located ***proximal*** to the orifice 558. As discussed with regard to Landau above, claim 1 specifies that the injection prevention component is disposed generally proximal to the cap distal face and ***distal*** to the distal end orifice. As such, Landau et al. does not teach or suggest every limitation of claim 1 from which claims 2-27 depend.

Moreover, as discussed above, Brignola does not suggest or teach the limitation in claims 1-27 of "an injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice."

Therefore, because the combination of Landau in view of Landau et al. and further in view of Brignola fails to teach or suggest every feature of claims 2-27, a prima facie case of obviousness has not been shown. Accordingly, Applicants respectfully request withdrawal of the §103(a) rejection of claims 2-27.

Landau In View Of Landau et al. and Further In View Of Brignola Does Not Render Claims 29-32 Obvious

Claims 28-32 of the present application recite "a means for preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice." As will be fully explained below, the combination of Landau in view of Landau et al. and further in view of Brignola fails to teach or suggest "a means for preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice."

In addition to the teachings discussed above, Landau further discloses a lock on the ***triggering mechanism*** of the device 10, whereby it is not possible to trigger the device 10 until body portions 12b and 12c are rotated so as to bring projection 24 into of alignment with recess 28 on trigger sleeve 22 (Landau at 7:21-30). However, claim 28 of the present application recites a means for preventing the ***injection piston*** from moving from a ***locked position*** wherein the means are partially located ***distal*** to the distal end orifice. Accordingly, Landau does not disclose any means for preventing the ***injection piston*** itself from moving or that the injection

piston itself can be locked in place or has a locked position. Rather, Landau discloses only a means for preventing the actuation of the ***triggering mechanism*** of the device, thus preventing the trigger from being depressed but not actually locking the injection piston in place within the device. More importantly, even if the trigger locking device in Landau can arguably be construed to be a means for preventing the injection piston from moving, the trigger locking mechanism of Landau is located ***proximal*** to the injection orifice 18. However, presently amended claim 28 recites that the means for preventing the injection piston from moving are partially located ***distal*** to the distal end orifice (i.e. injection orifice). As such, Landau does not teach or suggest a means for preventing the injection piston from moving from a locked position to a discharged position that is partially located ***distal*** to the distal end orifice, as is recited in claim 1. Accordingly, Landau does not disclose every limitation of claims 28-32.

The deficiencies of Landau are not cured when combined with Landau et al. As discussed above, Landau et al. illustrates (Figs. 12A, 17A and 17B) and describes (Landau et al. at 6:37 to 6:60, and 7:59 to 8:13) the use of an aluminum seal (168 or 568) and an elastomeric membrane (166 or 566) to seal the prefilled cartridge (112 or 512). The aluminum seal (168 or 568) and elastomeric membrane (166 or 566) are designed to burst open when loaded into a needleless injector and prepared for use. (Landau et al. at 6:51-60). Neither the aluminum seal (168 or 568) nor the elastomeric membrane (166 or 566) of Landau et al. teach or suggest ***a means for preventing the injection piston from moving from a locked position***, as the seal and membrane do not have any connection to the injection piston and do not prevent the injection piston from moving. Accordingly, they do not serve as a ***means for preventing the injection piston from moving*** as is recited in presently amended claim 28. Furthermore, Landau et. al does not disclose any features that are located ***distal*** to aperture 52 (i.e. the distal end orifice). As such, any feature disclosed in Landau et al. that could possibly be construed as a means for preventing the injection piston from moving would still not satisfy the claim 28 limitation that the means for preventing the piston from moving are partially located ***distal*** to the distal end orifice. As such, Landau et al. does not disclose, either explicitly or inherently, every limitation of claims 28-32.

Moreover, as discussed above, Brignola does not suggest or teach the limitation in claims 28-32 of "a means for preventing the injection piston from moving from a locked position to a discharged position wherein said means are partially located distal to the distal end orifice."

Therefore, because the combination of Landau in view of Landau et al. and further in view of Brignola fail to teach or suggest each and every limitation of independent claim 28 and claims 29-32 which depend therefrom, claims 28-32 are not rendered obvious. Applicants respectfully request that the §103(a) rejection of claims 29-32 be withdrawn.

The Method Steps of Claim 33 Are Not Inherent to Either Landau or Landau et al.

Claim 33 stands rejected under 35 U.S.C. § 103(a) as inherent to the apparatuses of Landau and Landau et al. In order for a reference to inherently disclose a claim limitation, that limitation must necessarily be present in the reference and be so recognized by a person of ordinary skill in the art. *Electro Medical Systems S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 32 USPQ2d 1017 (Fed. Cir. 1994). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (C.C.P.A. 1981).

Claim 33 specifies that the injector has a distal end orifice and that the locking mechanism is partially located distal to the distal end orifice. Additionally, claim 33 as filed contains the steps of "loading a cap" and "removing a cap." Thus, as set forth by these method steps, the cap is removable. However, neither Landau nor Landau et al. teach a removable cap, nor do the references (alone or in combination) teach a locking mechanism that is partially located ***distal*** to the distal end orifice, as previously discussed above. Due to the deficiencies of Landau in view of Landau et al. the method of claim 33 cannot necessarily result from the apparatuses described in Landau and Landau et al. Applicants respectfully request that the § 103(a) rejection of claim 33, based upon Landau in view of Landau et al., be withdrawn.

Concluding Remarks

Applicants submit that in light of the arguments provided herein, all pending claims of the present Application are in condition for allowance. Applicants respectfully request allowance of the claims. If, in the opinion of the Examiner, a telephone conference would help expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

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